

Tim Fagan's Law expands FDA authority to end the sale of dangerous counterfeit drugs; WHO says counterfeit drugs are a \$35 to \$40 billion a year industry ***Tim Fagan's Law expands FDA authority to end the sale of dangerous counterfeit drugs; WHO says counterfeit drugs are a \$35 to \$40 billion a year industry***

Washington, DC – On Tuesday, Rep. Steve Israel announced the introduction of the Counterfeit Drug Enforcement Act of 2009, also known as Tim Fagan's law. The legislation expands FDA authority to combat the distribution and sale of dangerous counterfeit medications.

"I first learned about the dangers of counterfeit drugs from my constituent, Kevin Fagan. The drugs he purchased from a national drug store chain on Long Island turned out to be fake and wreaked havoc on his son, Tim," said Rep. Israel. "We must do everything in our power to combat the counterfeiters and stop the distribution of these dangerous drugs. My legislation will give the FDA expanded authority to protect consumers."

Tim Fagan received counterfeit medication in place of the prescription he needed following a liver transplant. The pills he received only had a small amount of the medicine he actually required.

"It is our hope and our prayer that other parents will not have to see their child suffer the way we watched Tim suffer," said Kevin Fagan. "Over the years since Tim's agonizing experience with counterfeit drugs, much has been done privately to help secure our nation's drug supply system. But it is clear that much more still needs to be done. As long as drug prices remain high there is ample motive for counterfeiters to sell their dangerous wares. Tougher laws are needed to protect consumers from criminals infiltrating the supply chain and preying upon those who are most vulnerable – those in need of life-saving medicine."

Counterfeit drugs are defined as those without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or with fake packaging. The World Health Organization estimates counterfeit drugs are a \$35 to \$40 billion a year industry.

Tim Fagan's Law to combat counterfeit drugs will:

- Give the FDA recall authority, the same way the FDA can recall faulty medical equipment;
- Increase criminal penalties for counterfeiting;
- Mandate that drug manufacturers alert the FDA in 2 days when they learn that one of their drugs has been counterfeited;
- Authorize funds specifically for spot-checking (\$300 million over 5 years);
- Provide the FDA with the authority to require companies to use anti-counterfeiting technology;

- Require the FDA to remove the stay placed on paper pedigree requirements, which were mandated in the Prescription Drug Marketing Act of 1988;
- Authorize \$5 million for each year between fiscal years 2010 and 2014 for educating the public and health care professionals on how to identify counterfeit drugs; and
- Authorize the FDA to issue subpoenas with respect to preventing threats to public health.

Rep. Israel has led the charge against counterfeit drugs for the last seven years. His efforts are documented as part of the book *Dangerous Doses* by Katherine Eban.

Rep. Israel serves on the House Appropriations Committee.